510(k): K092565

510(k) Summary

Prepared: June 29, 2009

MAR 18 2010

Submitter/Holder:

Company Name:	Canon Inc.
Company Address:	30-2 Shimomaruko 3-chome, Ohta-ku Tokyo 146-8501, Japan
Contact Person:	Sheila Driscoll (from U.S. agent for Canon Inc.)
Phone Number:	516-328-5602
Fax Number:	516-328-5169

Proposed Device:

Reason For 510(k):	New Model
Trade Name:	Canon
Model Name:	CX-1
Classification Name(s):	86HKI Ophthalmic camera 86NFJ System, image management, ophthalmic
FDA 510(k) #:	To be assigned

Predicate Device:

Trade Name:	Canon
Model Name:	CF-1
Classification Name:	86HKI Ophthalmic camera
FDA 510(k) #:	K063717
Trade Name:	Canon
Model Name:	CR-1
Classification Name:	86HKI Ophthalmic camera
FDA 510(k) #:	K080883

Description of Device:

The DIGITAL RETINAL CAMERA CX-1 is used for taking digital images of retina of human eye with non-mydriatic and mydriatic.

Digital Camera (Dedicated) is mounted with CX-1, can be viewed immediately, making procedures more efficient and many different applications, such as telemedicine and electronic filing.

Intended Use:

The device is intended to be used for taking digital images of retina of human eye with non-mydriatic and mydriatic.

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Appendix G: Summary

Comparison to Predicate:

The differences between CX-1 and CF-1 and CR-1 are as follows;

	CX-1	CF-1	CR-1
Type	Mydriatic Non-Mydriatic	Mydriatic	Non-Mydriatic
Angle of view	Mydriatic: 50 degree Non-Mydriatic: 45 degree	Mydriatic: 50 degree	Non-Mydriatic: 45 degree
Photography mode	<5 modes> COLOR FLUO RED FREE COBALT FAF* *Fundus Autofluorescence angiography	<4 modes> COLOR FLUO RED FREE COBALT	<1 mode> COLOR
Attachable Digital camera	Bundled	None	None

Conclusion:

The Performance Data demonstrate that CX-1 is as safe and effective as the predicate devices. Based on the information in this submission, similarity to the predicate devices (the DIGITAL RETINAL CAMERA CF-1 and the DIGITAL RETINAL CAMERA CR-1), and the results of our design control activities and non-clinical testing, it is the opinion of Canon Inc. that the DIGITAL RETINAL CAMERA CX-1 described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Canon, Inc.
c/o Mr. Jeff D. Rongero
Underwriters Laboratories, Inc.
12 Laboratory Dr.
Research Triangle, NC 27709

MAR 1 8 2010

Re: K092565
Trade/Device Name: Digital Retinal Camera CX-1
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Codes: HKI, NFJ
Dated: March 2, 2010
Received: March 3, 2010

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

510(K)Number (if known) : K092565

Device Name: CX-1

Indications for Use:

The device is intended to be used for taking digital images of retina of human eye with non-mydriatic and mydriatic.

Prescription Use X **OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K092565